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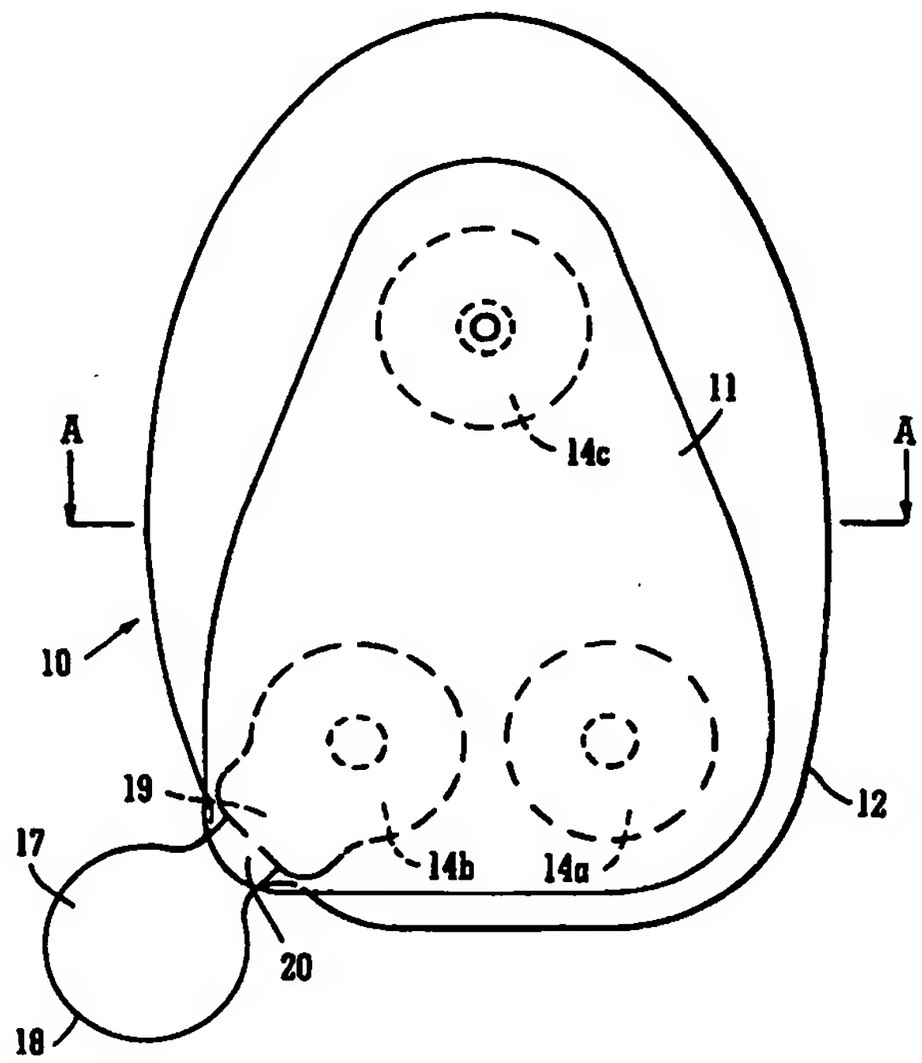
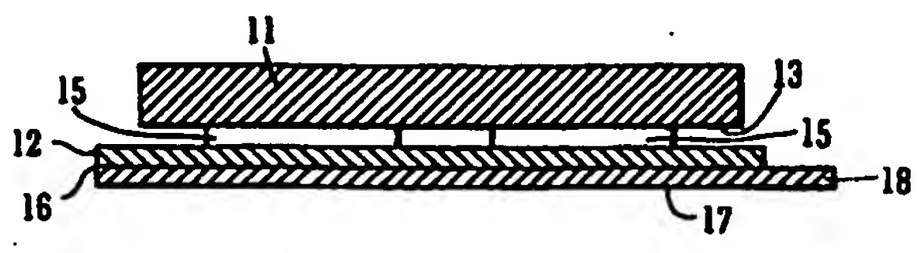
(54) Title: ADHESIVE SYSTEM FOR ATTACHING MEDICAL DEVICES TO A SURFACE

(57) Abstract

A system (10) adapted to be disposed between a rigid or semi–rigid device (11) and human skin for reliably attaching the device to the skin for an extended period of time. The system includes a skin–contacting surface for adhering to human skin, and an opposed surface for attachment to a rigid or semi–rigid device. The system is attached along its opposed surface to a portion (14a, 14b, 14c) of the total area of the adjacent surface of the device. When the device is subjected to external stress, the stress is transmitted through the area of attachment (14a, 14b, 14c) and distributed to the unattached area. This minimises stress on the skin and reduces the chance of detachment from the skin.





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Description

ADHESIVE SYSTEM FOR ATTACHING MEDICAL DEVICES TO A SURFACE

Technical Field

This invention relates generally to systems for attaching rigid or semi-rigid structures to human skin, and in particular to medical devices for attachment to the skin of the human body.

Background Art

There are certain types of ambulatory medical devices such as miniature infusion pumps, iontophoretic devices and the like that are designed to be attached to human skin during use. Due to the nature of these devices many are rigid and attachment to the skin for a prolonged period of time has been unsuccessful. It is difficult to successfully adhere a rigid device to the skin surface for a prolonged period of time due to the rigidity of the device, the geightened center of gravity above the adhesion level, and the flexibility and pliability of the skin.

Rigid devices of the type disclosed in WO 97/10012 are presently applied to the skin by means of pressure sensitive adhesive. These devices show signs of failure within 24 hours of attachment and have completely detached before 48 hours have elapsed from the time of application. Such devices will be collectively referred to herein as rigid devices, except where otherwise specified.

Commercially available bandages or skin adhering tape employ the same types of pressure sensitive adhesive and reliably adhere to the skin for long periods of time, for example for one or more week(s). Conventional pressure sensitive adhesives consist generally of silicone, butyl or acrylic components that are formulated in such a way so that reliably adhere to the skin.

Bandages or skin adhering tape and presentattachment means for rigid devices extend the adhesive to the edge of the device which is adhered to the skin.It is at the interface between the rigid device and the skin that challenges adhesion, particularly in the case of rigid devices, and causes system failure.

The detachment of rigid devices from the skin typically occurs when there is a failure in the underlying skin integrity leading to separation of the device along with the outer skin layers. Reactions to external stress are responsible for most device to skin adhesion failures. In this regard, the areas of skin of greatest concern are the outermost layers of the epidermis, more particularly the *stratum corneum.* In this region of the skin there are multiple cell layers (as many as 150) which are held together or bonded by nodes known as desmosomes resulting in a flexible three-dimensional web. Although usually viewed as dead skin cells, the *stratum corneum* is, in fact a dynamic functional portion of the epidermis that provides protection for the lower skin layers. The structure of the *stratum corneum* is very compliant and has the ability to easily relieve stress applied thereto, thereby avoiding disruption of lower layers and maintaining the integrity thereof. When the skin is stressed, deep skin fracture is prevented because of the rupture of desmosome bonds through fatigue resulting in relief of stress through sloughing of surface layers of skin cells.

Skin is almost unmatched in its compliance and ability to relieve stresses. In particular, skin is about forty times more compliant than any commercially available pressure sensitive adhesive. Even the most compliant vinyl carrier for an adhesive will be about one hundred and thirty times less compliant than skin. A moulded plastics part of the type represented by a rigid device does not provide any compliance and would be close to zero on a relative compliance scale. Anything attached to the *stratum corneum* applies a stress to the skin. Thus, because of the difference in compliance between a rigid device and the skin there will always be a shear force between the skin and an adhesive system used to adhere said device to the skin. As indicated above, the skin relieves any stress by shearing.

Presently, rigid medical devices are completely attached along the lower surface to the skin by means of adhesive. The resultant rigid attachment maximises the stress potential on the skin leading to early signs of detachment and often complete detachment prior to the completion of the treatment provided by the device.

In addition, medical devices that infuse drug into a patient typically require the drug to travel from a container distal to the point of infusion. This results in a drug temperature change or flux that may be harmful to the efficacy of the drug and patient. Accordingly, there is a need for a skin adhesive system that will adhere a rigid device to the skin for extended periods of time for use in effective therapy and diagnosis. Any such device should provide for both secure attachment and easy removal of the device. In addition, effective adhesive systems for use in connection with infusion systems should minimize the temperature flux of the drug which may optimize efficacy and overall patient benefit.

Disclosure of Invention

The present invention provides a system adapted to be disposed between a rigid or semi-rigid device and human skin for reliably attaching the device to the skin for an extended period of time, the system having a skin-contacting surface for adhering to the skin and an opposed surface, for attachment to the device over a portion of the total area of the adjacent surface of the device thereby minimising stress on the skin and reducing the tendency of the device to detach from the skin.

The system transmits any external stress to which the device is subjected and distributes it to the unattached areas of skin proximate to the adjacent surface of the device.

The system according to the invention provides for secure skin attachment for extended periods of time and easy removal of the device, when required. The system provides for superior performance relative to known systems and in tests has shown suitability for application to multiple

sites and three-day operation or longer. In particular, the system according to the invention has been shown to be effective for more than 72 hours of secure device attachment to the skin while allowing the wearer to undergo the normal activities of daily life.

The system according to the invention by virtue of its construction provides sufficient relaxation of any stress before transition thereof to the skin. It will be appreciated that the lower the magnitude of any stress imparted to the skin, the better.

In one embodiment, the system comprises a structure which is a laminar element.

Preferably, the system extends beyond the adjacent surface of the device.

An important aspect of the present invention is that it minimises the forces on the interface between the device and the skin at the edge of the adhesive. This area must be the most compliant area of the system.

Thus, preferably each area attached to the skin is located towards the centre of the system so as to allow for flexibility towards the periphery thereof.

Further, preferably, the skin contacting surface comprises a pressure sensitive adhesive.

Still further, preferably, the system comprises a carrier element having viscoelastic properties approaching those of skin.

The carrier must be made of a compliant material or otherwise be capable of even distribution of stress, more especially a material that minimises local stress on the skin when a stress is applied to the device.

In a preferred embodiment, the system is attached to the adjacent surface of the device at a number of discrete areas.

Typically, three discrete areas or anchor points will be used.

Suitably, the areas of attachment to the device are arranged at the apices of a triangular area or other regular pattern or shape.

Thus, the structure is attached to the device over a limited area leaving the rest of said structure to move freely with the skin. This creates a flexible 'skirt' around each discrete attached area. Maximisation of the flexible area in the system according to the invention is a key component in the adhesion longevity achieved.

Extended wear time with the system according to the invention is accomplished by minimising the stresses imparted to the skin that cause local skin fatigue failure and eventual detachment of the device. The construction embodied in the system according to the present invention allows the skin to move more freely than in the case of prior art systems, thereby reducing the magnitude of any stresses on the skin.

The system can be permanently attached to the device at each area of attachment.

Alternatively, the system is detachable from the device.

This feature allows the device to be replaced without detaching the skin-contacting surface from the skin.

The system according to the invention can be used with any product that has a rigid or semi-rigid construction and has to be attached to the human body. Such devices include: infusion systems of the type covered by International Publication No. WO 97/10012; iontophoretic drug delivery systems; minimally invasive sensors, including glucose sensors; diagnostic devices such as devices used in heart rate, pulse and ECG monitoring;

ostomy products; nerve stimulators; external programming, data collection and monitoring devices for pace makers and defibrillators; implantable hearing aids and the like.

In one embodiment, the system is attached to the device by means of the co-operating elements of a fastening system located on the base of the device and the opposed face of the system, respectively.

Adhesive attachment of the system to the device can be achieved by means of a locally applied adhesive such as a pressure sensitive, epoxy or heat or UV-activated adhesive.

In a further embodiment, the device is provided with a relief cavity which can accommodate deflection of the skin in use which would otherwise result in higher stress and a detachment thereof.

Thus, the base of the device can be contoured to allow a maximum flexibility in relation to the skin. For example, the base of the device can be designed with a concave or relieved area. This creates an area for skin to flex into during physical activity without it pressing against the device and thus increasing stress on the skin.

The relief cavity can be a concave area in the base of said device.

The device to be applied to the skin may be provided with an integral needle for delivery of a substance through the skin.

With such devices, a flexible area is preferably provided at the locus where the needle penetrates the structure for access to the skin.

The area where the needle penetrates the skin is also an adhesive edge and adhesion longevity is improved by creating a flexible skirt around the hole resulting from or allowing for the needle penetration. This flexible skirt would typically extend 1-2mm radially from the adhesive edge. This skirt allows for stress relief when the needle moves in relation to the skin.

By providing a flat section around the area where the needle penetrates the system concentrates pressure against the skin during application. This allows maximum wetting of the skin surface by the adhesive to ensure effective device operation.

Also suitably the system is provided with a 2-3mm diameter hole through which the needle penetrates.

A 2-3mm diameter hole in the skin adhesive allows the device needle to the inserted into the skin without having to pass through the adhesive layer. The small size of the hole is necessary so that the skin remains taut to ensure penetration thereof by the needle.

Preferably, one area of attachment is provided with an extension to the periphery of the system which facilitates removal of the device when required.

In a further aspect of the invention there is provided a method for reliably attaching a rigid or semi-rigid device to human skin for extended period of time, comprising the steps of:

providing a system having a skin-contacting surface for adhering to human skin and an opposed surface for attachment to a rigid or semi-rigid device;

attaching the opposed surface to a portion of the total area of the adjacent surface of the rigid or semi-rigid device; and

attaching the skin-contacting surface to the skin, whereby when the device is subject to external stress, thereby minimising stress on the skin and reducing the chance that the device will detach from the skin.

The adhesive system of the present invention may be used in connection with an infusion device. By effectively adhering the infusion device having drug contained therein to the user, the temperature flux of the

drug is minimized. This increases the efficacy of the drug and results in overall benefit to the patient.

Other objects, features and advantages of the present invention will become apparent upon reading the following detailed description of the embodiments of the invention, when taken in conjunction with the drawings and appended claims.

Brief Description of Drawings

The invention will be further illustrated by the following description of embodiments thereof given by way of example only with reference to the accompanying drawings in which:

Fig. 1 is a plan view of a preferred embodiment of the system according to the invention;

Fig. 1A is a cross-sectional view of the preferred embodiment of Fig. 1;

Figs. 2A-C are schematic representations of various discrete areas of attachment employed in the system according to the invention with an indication of adhesion strength *versus* ease of removal for the respective variations;

Fig. 3 is a top view of the system according to the invention showing discrete areas of attachment and a local failure point;

Figs. 4A-E are cross-sectional views depicting various options for attachment of the system according to the invention to a rigid or semi-rigid device;

Fig. 5 is a cross-sectional schematic representation of the base and needle of a device as attached to the skin using a system according to the invention; and

Fig 6 is a further cross-sectional schematic representation of the base and needle of a device as attached to the skin using a system according to the invention.

Modes for Carrying Out the Invention

Referring to Fig. 1 of the drawings there is indicated, generally at 10, part of a system according to invention which enables a rigid or semi-rigid device 11 to be reliably attached to the skin of a human body for an extended period of time. The system as shown in Fig. 1A includes a structure, indicated generally at 12, which is disposed in the interface between the device 11 and the skin (not shown). The device has a base 13 and is attached to the structure 12 on its upper surface opposed to the base of the device at three areas 14a, 14b and 14c by means of adhesive 15. The structure 12 has a skin-contacting surface 16, which is adhered to the skin in use by means of a pressure-sensitive adhesive.

Such pressure sensitive adhesives include acrylic, butyl, hydrogel, polyisobutylene, silicone and the like adhesives. Adhesives will suitably be the same as those used in commercially available bandages and sticking plasters. However, Avery Fastape, a double sided polyester film tape is preferred. Moreover, the thickness of the adhesive should be between 1.5 and 2.0 mils.

The skin-contacting surface 16 is covered with a conventional release liner 17 prior to use. The release liner 17 is removed by means of a tab 18.

The release liner can be composed of a variety of materials due to the cancelled adhesive area which will typically be a feature of the system according to the invention. Standard release liners made of low cost siliconised paper or plastic film can be employed. If the cancelled area is not present a more expensive flourosilicone-coated premium release liner or centre butterfly tab would be required to avoid tearing the liner or damage to the adhesive attachment.

The system *per se* can be a layer of a polymeric material with the requisite properties and having a skin-contacting surface.

Alternatively, the laminar element can be a layer of double-sided adhesive material of sufficient rigidity.

As shown in Fig. 1, attachment area 14b has an extension 19 which terminates just short of edge 20 of the structure 12. This feature serves to aid removal of the device 11 from the skin (not shown) when required, because failure of the adhesive tends to occur at this point. Positioning the extension 19 near the liner removal tab 18 allows for easy removal of the liner 17 also.

By locating the area of attachment close to the edge of the skin-contacting surface, removal forces are lowered. This occurs because the area of attachment is cancelled at this point and a mechanical advantage can be obtained for peeling off the device. The result is a localised adhesion force reduction over time that allows the edge of the adhesive to lift. The user can take advantage of this and start the removal process by peeling off the device from this point. Positioning this 'cancelled area' near the removal tab, which will be provided on the release liner, allows for easy removal of the liner also.

Referring to Figs. 2A-2C there are depicted three variations of the discrete area or areas of attachment employed in a system of the type depicted in Fig. 1.

Fig. 2A corresponds to the system used in Fig. 1 and Figs. 2B and 2C represent situations where the three areas of Fig. 2A are joined by areas of adhesive.

As indicated by the labelled arrows, the smaller the area of the structure 12 attached to the device 11, the greater the adhesive strength of the system and the more difficult it is to remove the device from the skin and *vice versa*.

It will be appreciated that the greater the area that is rigidly connected to the device, the larger the magnitude of the stress that can be imparted to the skin causing a reduction in adhesion force over time and facilitating removal. Adhesion life and ease of removal are inversely related. Thus, by connecting the adhesion points or enlarging them, one facilitates ease of removal of the device, when required.

Referring to Fig. 3, there is indicated part of the structure 12 depicted schematically in Fig. 1 viewed from above showing the areas of attachment 14a-14c disposed on surface 21 of the structure 12 to which the device is attached. The arrangement of the extension 19 of the attachment area 14b stopping just short of the edge of the surface 21 creates a local failure point which facilitates removal of the device 11 when required.

Figs. 4A-E show various options for attaching the structure 12 used in the system 10 according to the invention to the device 11. In Figs. 4A-E, the same reference numerals are used to depict the same parts.

In Fig. 4A there is shown base 30 of the device 11 to be secured to skin 31 of a human being using the system 10 according to the invention. Base 30 is attached to surface 32 of a structure 33 at three areas 34 of adhesive. The structure 33 is comprised of a carrier element 35 having viscoelastic properties approaching that of skin provided with a layer of pressure sensitive adhesive 36 on its skin-contacting surface 37.

The carrier element, when such is present, can be formed from foams, especially flexible foams manufactured by Kendall Polychem or Avery Dennison. In particular, the preferred foams included Actiflex™ made by

Kendall Polychem and PVC1, a PVC closed cell foam made by Avery Dennison under the model number Q527297. be made of woven and non-woven fabrics. A suitable non-woven fabric is a spun-laced polyestermarketed by Du Pont under the mark SONTARA.

In Fig. 4B, the device is attached to the structure 33 by means of rivets 38 which extend through the structure.

In Fig. 4C, the device 11 is attached to the structure 33 by means of a one-way snap attachment 39. In this embodiment, the device 11 is not removable from the structure 33.

In Fig. 4D, the device 11 is attached to the structure 33 by means of a removable snap attachment 40.

In Fig. 4E, the device is attached to the structure 33 by means of a hook and loop attachment means 41.

In the case of the embodiments depicted in Fig. 4D and 4E the device is detachable from the structure 33, so that the structure can be left in contact with the skin and a further device attached thereto, if required.

Alternatively, attachment of the system to the device can be achieved by means of rivets, snaps, including mechanical snaps, heat, including posts for heat staking, or sonic welding, spring clips, hook and loop fasteners such as VELCRO® and magnetic fastening means or a combination thereof.

Fig. 5 illustrates a typical cross-sectional view of a medical device 42, with an integral needle 43, attached to a structure 44 at areas 45 and 46. Structure 44 is free to move where the device 42 is not attached to the structure 44 (indicated at 47). There is also an unattached area 48 of structure 44 immediately surrounding the needle 41. The area 47 where the structure 44 is unattached can accommodate deflection of skin in use and relieve stress. Because drug is delivered through the needle and the drug

reservoir is effectively held proximate to the skin surface, the drug temperature will not change considerably prior to or during delivery. This is advantageous where drug temperature is sensitive and may change efficacy as temperature fluctuates. By maintaining a constant temperature, the drug is most effective and most beneficial to the patient.

Fig. 6 illustrates a further cross-section portion of a base 50 (shown in phantom) with an integral needle 51, attached to a structure 52 at areas 53 and 54. The structure 52 is free to move where the base 50 is not attached to the structure 52 shown at 55. There is also an unattached area 56 immediately surrounding the needle 51. The area 55 can accommodate deflection of skin in use and relieve stress.

It will be appreciated that the embodiments discussed above are preferred embodiments, and that various alternative embodiments are contemplated, falling within the scope of the appended claims.

CLAIMS:

1. A system adapted to be disposed between a rigid or semi-rigid device and human skin for reliably attaching the device to the skin for an extended period of time, the system comprising:

a skin-contacting surface for adhering to human skin; and

an opposed surface for attachment to a rigid or semi-rigid device over a portion of the total area of the adjacent surface of the device, thereby minimising stress on the skin and reducing the chance of detachment from the skin.

2. A system according to Claim 1, wherein when the device is subject to external stress, the stress is transmitted through the area of attachment and distributed to the unattached area.

3. A system according to Claim 1 or 2, wherein the system comprises a structure which is a laminar element.

4. A system according to Claim 3, wherein the laminar element has a skin contacting surface.

5. A system according to any preceding claim, which extends beyond the adjacent surface of the device.

6. A system according to any preceding claim, wherein each area attached to the skin is located towards the centre of the system so as to allow for flexibility towards the periphery thereof.

7. A system according to any preceding claim, wherein the skin contacting surface comprises a pressure sensitive adhesive.

8. A system according to any preceding claim, wherein the system comprises a carrier element having viscoelastic properties approaching those of skin.

9. A system according to any preceding claim, wherein the system is attached to the adjacent surface of the device at a number of discrete areas.

10. A system according to Claim 9, wherein the areas of attachment are arranged at the apices of a triangular area.

11. A system according to any preceding claim, which is permanently attached to the adjacent surface of the device at each area of attachment.

12. A system according to any one of Claims 1-10, which is detachable from the device.

13. A system according to Claim 12, which is attached to the device by means of the co-operating elements of a fastening system located on the adjacent surface of the device and the opposed surface of the system, respectively.

14. A system according to any preceding claim, wherein the device is provided with a relief cavity which can accommodate deflection of the skin in use which would otherwise result in higher stress and a detachment thereof.

15. A system according to Claim 14, wherein the relief cavity is a concave area in the adjacent surface of the device.

16. A system according to Claim 14 or 15, wherein the device is provided with an integral needle for delivery of a substance through the skin.

17. A system according to Claim 16, wherein a flexible area is provided at the locus where the needle penetrates the system for access to the skin.

18. A system according to any preceding claim, wherein one area of attachment is provided with an extension to the periphery of the system which facilitates removal of the device when required.

19. A method for reliably attaching a rigid or semi-rigid device to human skin for an extended period of time, comprising the steps of:

providing a system having a skin-contacting surface for adhering to human skin and an opposed surface for attachment to a rigid or semi-rigid device;

attaching the opposed surface to a portion of the total area of the adjacent surface of the rigid or semi-rigid device; and

attaching the skin-contacting surface to the skin, thereby minimising stress on the skin and reducing the chance of detachment from the skin.

20. A method according to Claim 19, wherein when the device is subject to external stress, the stress is transmitted through the area of attachment and distributed to the unattached area.

21. A method according to Claim 19 or 20, wherein the system comprises a laminar element.

22. A method according to Claim 21, wherein the laminar element has a skin contacting surface.

23. A method according to any one of Claims 19-22, wherein the system extends beyond the adjacent surface of the device.

24. A method according to any one of Claims 19-23, wherein each area attached to the skin is located towards the centre of the system so as to allow for flexibility towards the periphery thereof.

25. A method according to any one of Claims 19-24, wherein the skin contacting surface comprises a pressure sensitive adhesive.

26. A method according to any one of Claims 19-25, wherein the system comprises a carrier element having viscoelastic properties approaching those of skin.

27. A method according to any one of Claims 19-26, wherein the attachment to the adjacent surface of the device occurs at a number of discrete areas.

28. A method according to Claim 27, wherein the areas of attachment are arranged at the apices of a triangular area.

29. A method according to any one of Claims 19-28, wherein the attachment of the system to the device is permanent.

30. A method according to any one of Claims 19-29, wherein the system is detachable from the device.

31. A method according to Claim 30, wherein the attachment of the system to the device is accomplished by locating co-operating elements of a fastening system on the adjacent surface of the device and the opposed face of the system, respectively.

32. A method according to any one of Claims 19-31, wherein the device is provided with a relief cavity which can accommodate deflection of the skin in use which would otherwise result in higher stress and a detachment thereof.

33. A method according to Claim 32, wherein the relief cavity is a concave area in the adjacent surface of the device.

34. A method according to Claim 32 or 33, wherein the device is provided with an integral needle for delivery of a substance through the skin.

35. A method according to Claim 34, wherein a flexible area is provided at the locus where the needle penetrates the system for access to the skin.

36. A method according to any one of Claims 19-35 further comprising the step of providing an extension to the periphery of the system which facilitates removal of the device when required.

37. A system according to Claim 1 adapted to be disposed between a rigid or semi-rigid device and human skin for reliably attaching the device to the skin for an extended period of time, substantially as hereinbefore described with particular reference to and as illustrated in the accompanying drawings.

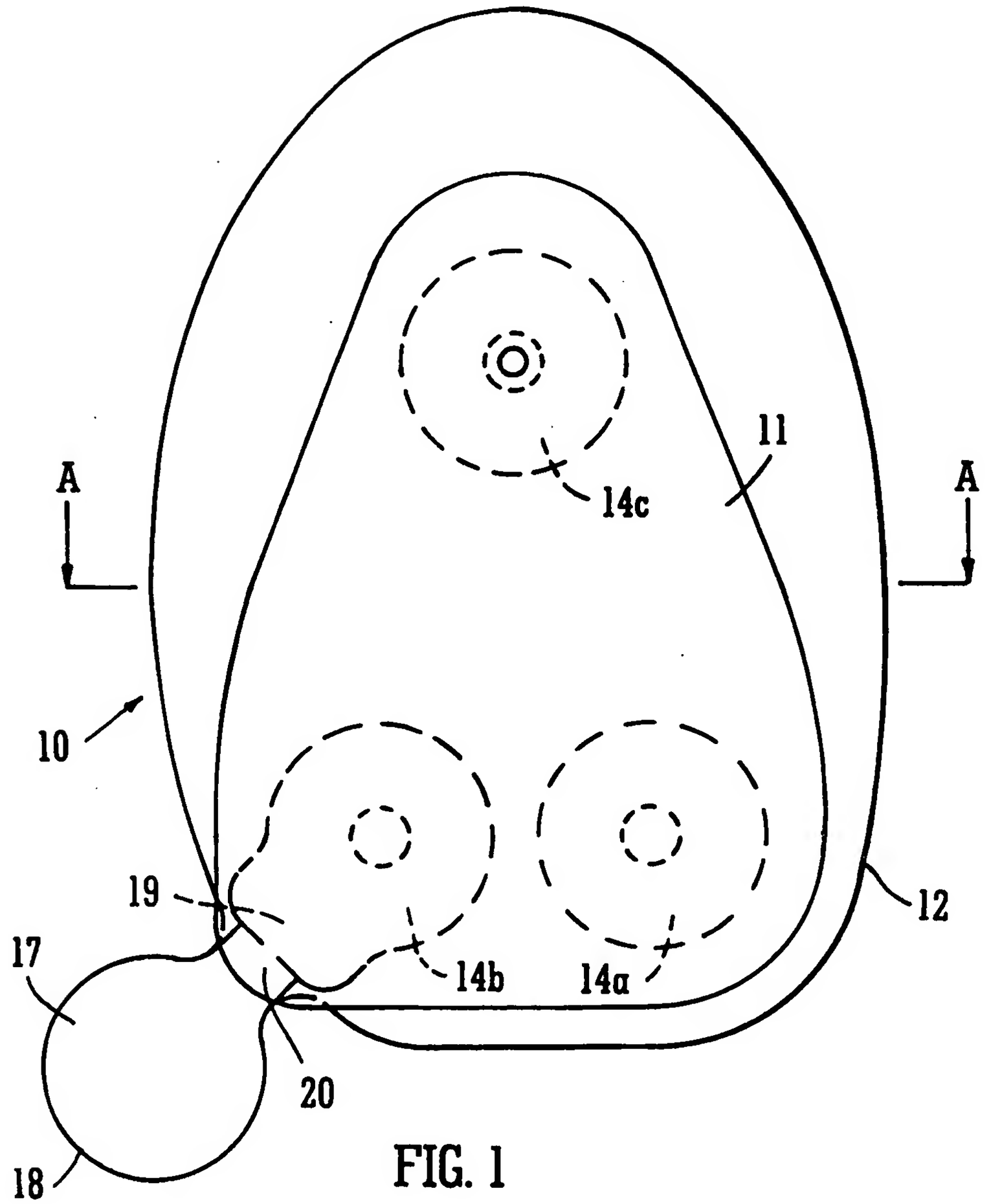

FIG. 1

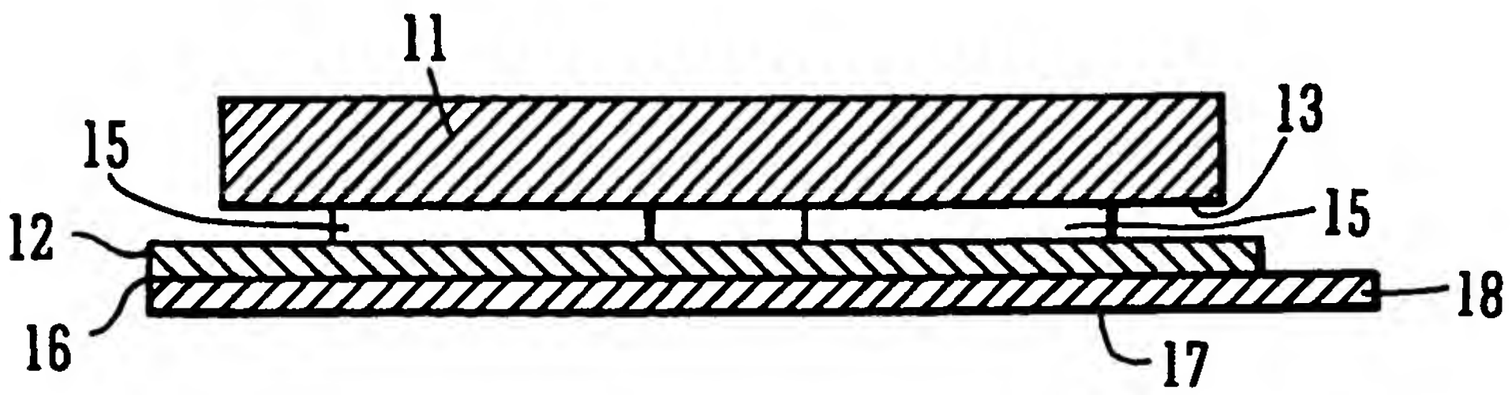

FIG.1A

ADHESION STRENGTH

EASY TO REMOVE

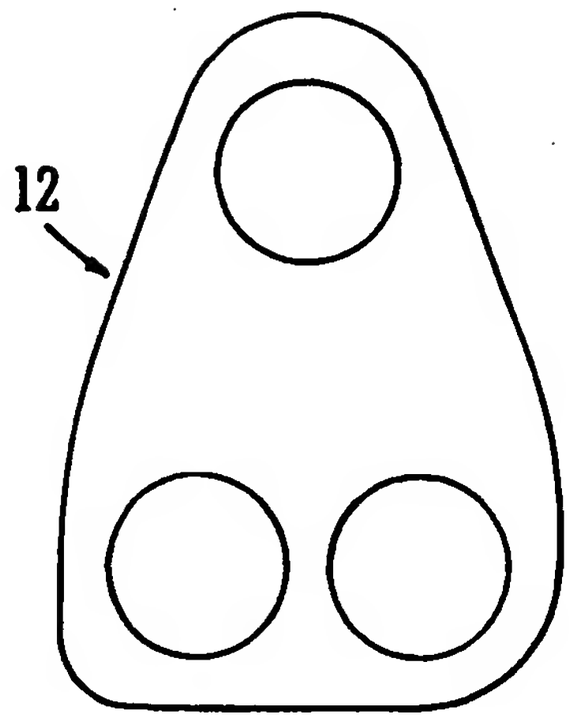

FIG. 2A

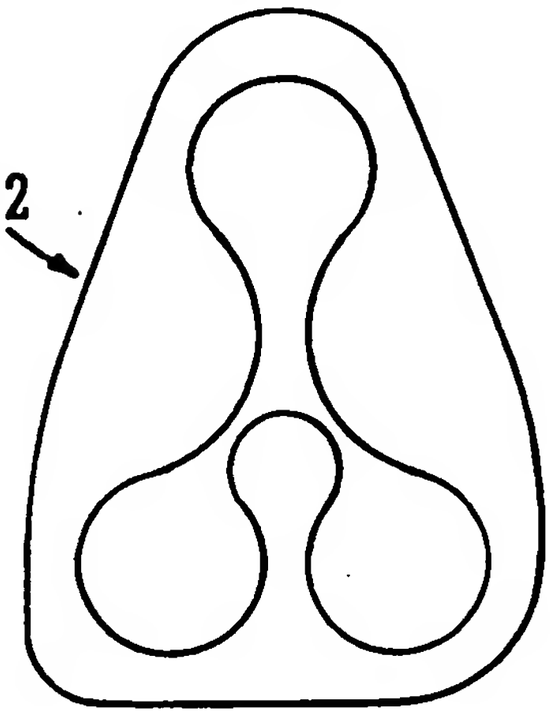

FIG. 2B

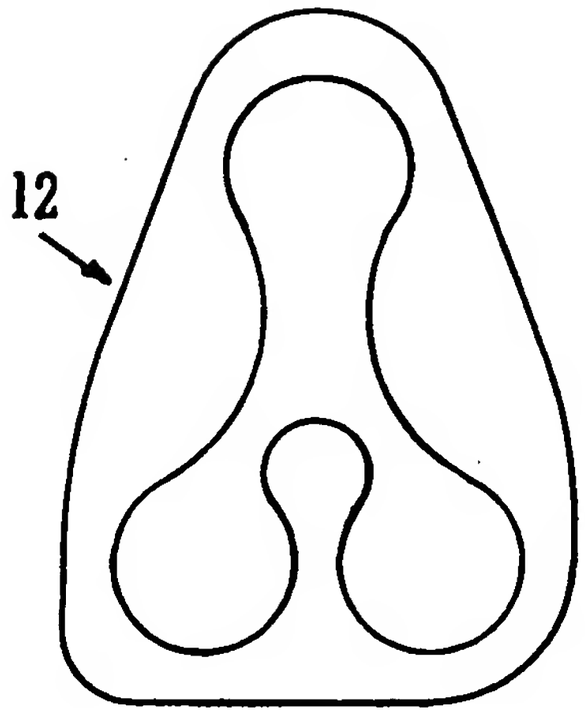

FIG. 2C

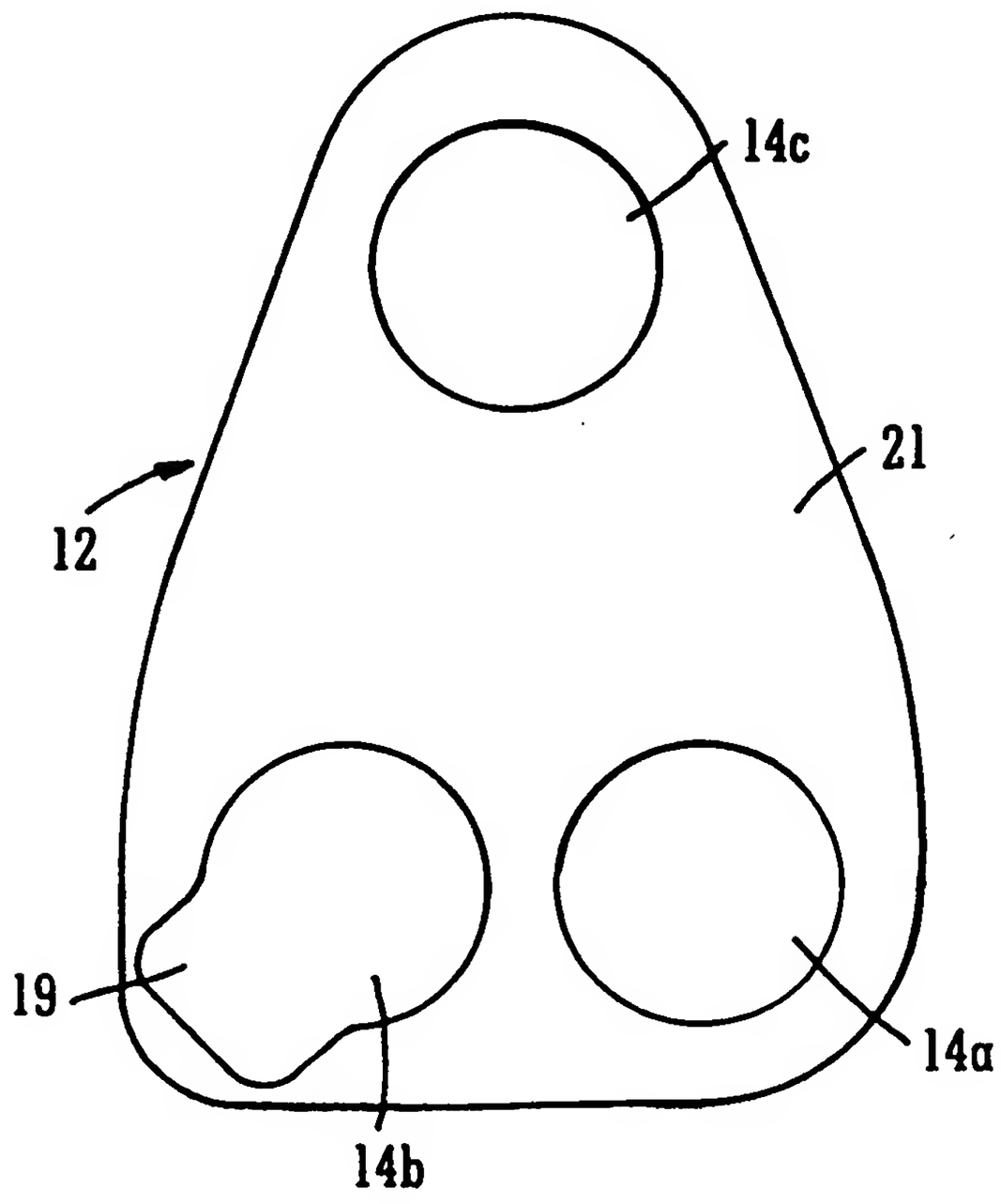

FIG. 3

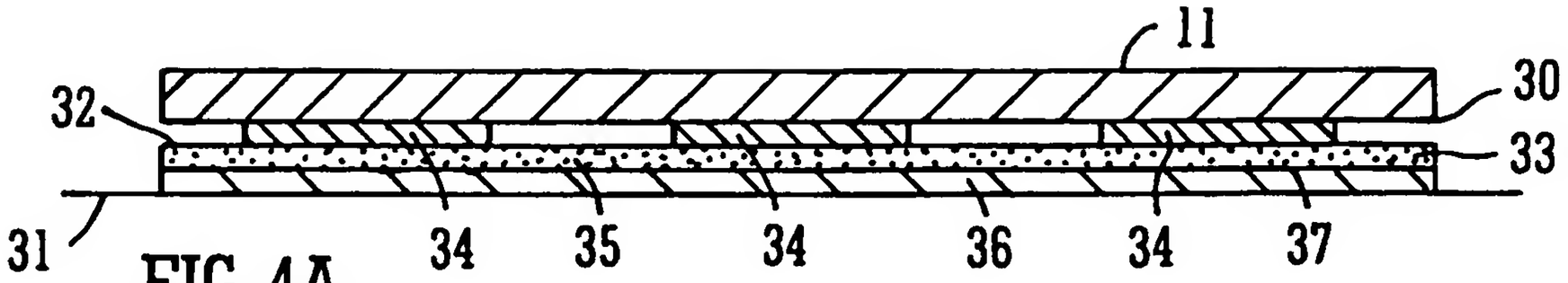

FIG. 4A

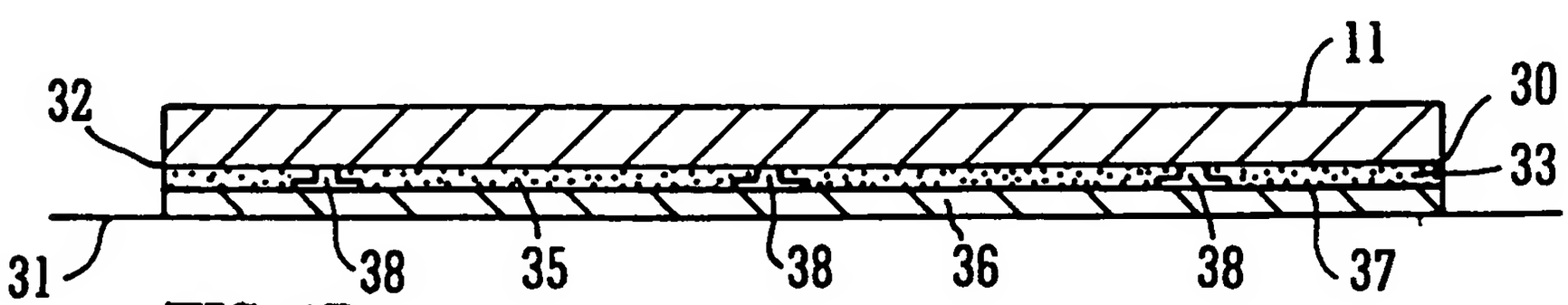

FIG. 4B

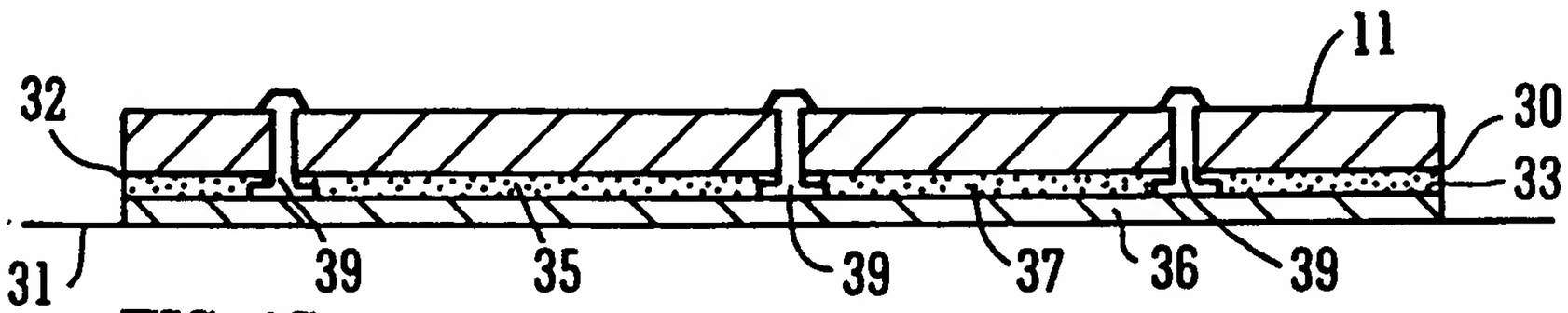

FIG. 4C

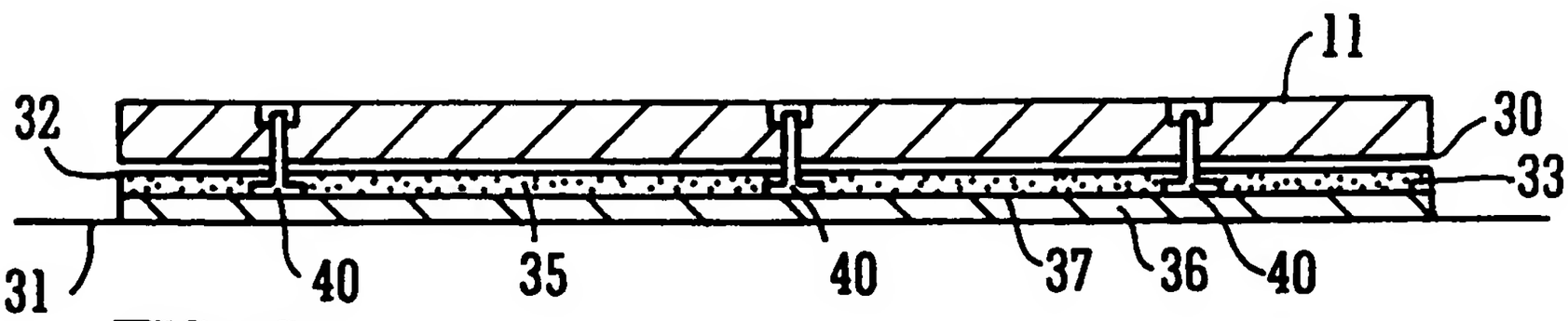

FIG. 4D

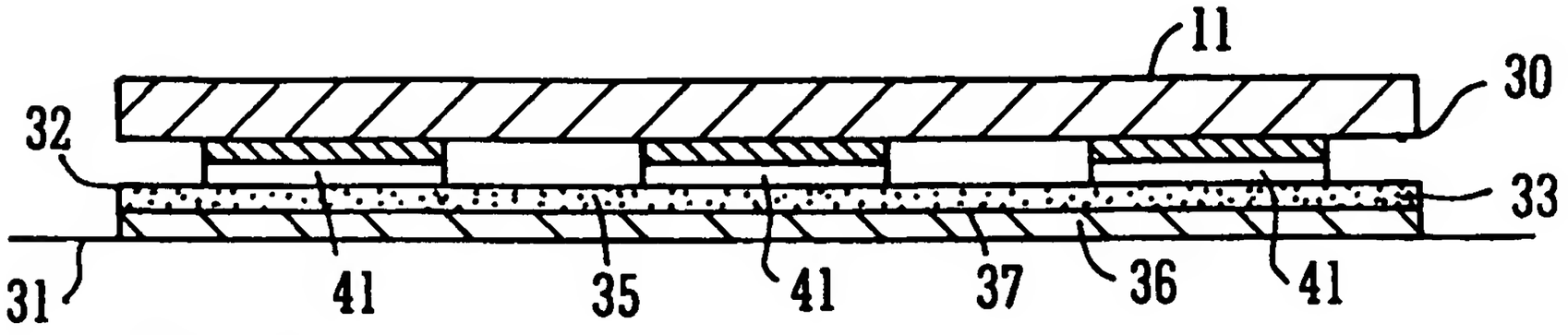

FIG. 4E

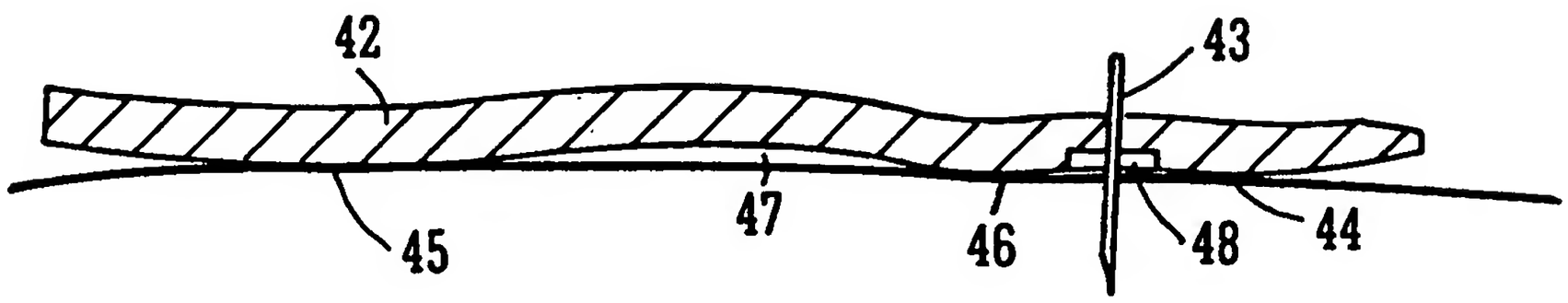

FIG. 5

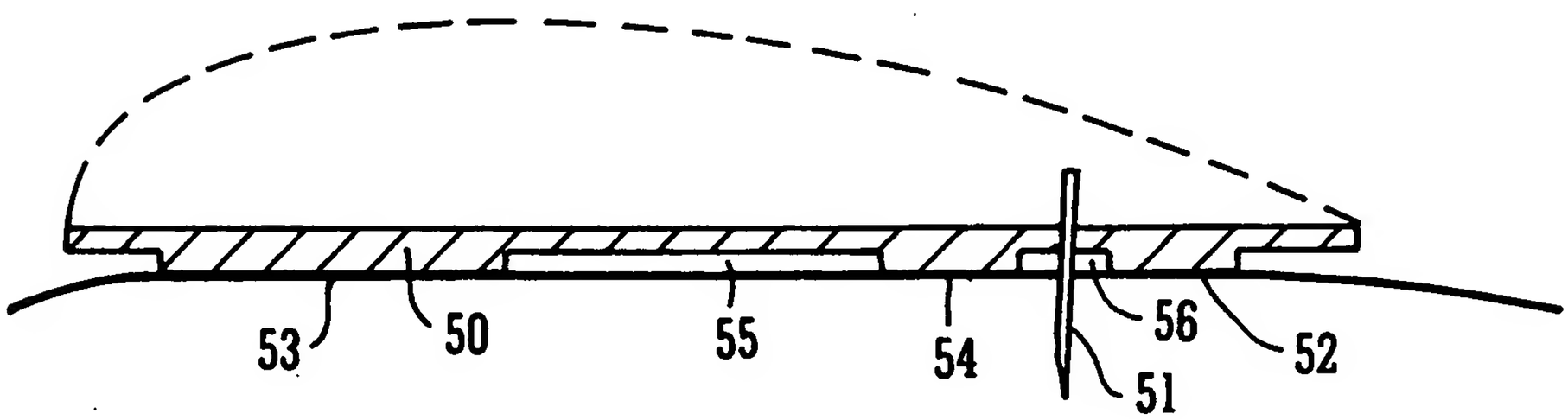

FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 99/00046

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 4 336 806 A (ELDRIDGE JR.) 29 June 1982 (1982-06-29) abstract; figures 1-9	1,2,5,6, 9-12,18 3,4,7,8, 13

Y A	EP 0 689 853 A (MINNESOTA MINING & MFG) 3 January 1996 (1996-01-03) abstract page 5, line 46 - line 53; claim 19; figures 2A-D,3A,4A,B	3,4,7,8 18-36

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 September 1999	15/09/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Michels, N

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